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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,407	12/05/2005	Yun-Hee Ku	P5102/JRIM	5617
41943 GWIPS PETER T. KWON P.O. BOX 231630 CENTERVILLE, VA 20120	7590	10/31/2007	EXAMINER STOCK JR, GORDON J	
			ART UNIT 2877	PAPER NUMBER
			MAIL DATE 10/31/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,407	KU, YUN-HEE	
	Examiner	Art Unit	
	Gordon J. Stock	2877	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 05 December 2005.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-11 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-11 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 05 December 2005 is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
5) Notice of Informal Patent Application
6) Other: _____.

DETAILED ACTION

Priority

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Drawings and Specification

2. The drawings and specification are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: 44 of Fig. 8. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

3. **Claims 1, 7, and 8** are objected to for the following: as for **claim 1**, 'the pressure difference' of line 6 and 'the diffracted images' of line 14 lack antecedent basis. Examiner suggests using -a pressure difference- and -diffracted images-. In addition, on line 17

'deformation on time' should read -deformation in time-. As for **claims 7 and 8**, 'the diffracted image' should read -the diffracted images-. Corrections required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 1-8** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The term "tiny" in **claims 1-3** is a relative term which renders the claim indefinite. The term "tiny" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. 'Tiny' renders the size of the blood sample pot and 'waste blood pot' indefinite. **Claims 4-8** are rejected for being dependent from a rejected base claim.

7. Regarding **claims 5 and 6**, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. **Claims 1-6, 9, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spence et al. (6,540,895).**

As for **claim 1**, Spence in an apparatus (col. 5, lines 48-53) discloses the following: a disposable blood test kit (Fig. 8: microfabricated cell sorting device; col. 3, lines 30-35; col. 8, lines 30-35); a light emitting unit (Fig. 8: coherent laser); a measurement unit (col. 8, lines 30-40; Fig. 8: PMT); disposable blood test kit comprises a blood sample pot, a slit channel, and a waste blood pot (Figs. 14a-14b); a differential pressure generator connected to the disposable blood test kit through a connecting tube and a valve (Figs. 5, 14a-14b, 15a-15b demonstrate multiple tubes; col. 3, lines 55-65); a screen (Fig. 8: video); an image capturing unit (Fig. 8: ccd camera); a control unit (pressure controller: col. 8, lines 44-55); an output unit and memory unit (Fig. 8: PMT, preamplifier with computer). As for the laser being disposed above said disposable blood test kit, Spence discloses the laser underneath the kit (Fig. 8: cell sorting device and coherent laser). However, he teaches that the cell sorting device may be completely transparent (col. 31, lines 30-40). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have the laser above the cell sorter for the transparency of the cell sorter makes the cells observable from above or from below. As for a pressure gauge, Spence does not explicitly state this, but he suggests this for pressures are controlled (col. 7, lines 44-55). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have a pressure gauge connected to the pressure generator and test kit in order to monitor pressure for proper pressure control of the system.

As for the following, 'for measuring blood cell deformability (line 1);' 'for directly containing blood sample (line 2);' 'for measuring the blood cell deformability (line 4);' 'for containing the blood sample (lines 5-6);' 'for flowing the blood sample by the pressure difference (line 6);' 'for collecting the tested blood sample (lines 7-8);' 'for generating the pressure difference between the tiny blood sample pot and tiny waste blood pot (lines 11-12);' 'for measuring the pressure difference (line 14);' 'for projecting the diffracted images of the blood cell (lines 14-15)' 'for capturing the diffracted images (line 15);' for calculating the blood cell deformability, variation of the shearing force, and deformation in time based on data received from the pressure gauge and the image capturing unit (lines 16-18);' 'for printing the calculated information on a sheet or displaying on an LCD screen (lines 18-19);' and 'for storing the calculated information and images (line 20)' it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. Ex Parte Masham, 2 USPQ F.2d 1647 (1987).

As for **claims 2-3**, Spence discloses everything as above (see **claim 1**). In addition, Spence discloses the differential pressure generator is connected to the waste/sample pot of the kit through a connecting tube and a valve valve (Figs. 5, 14a-14b, 15a-15b demonstrate multiple tubes; col. 3, lines 55-65).

As for the following, 'for generating vacuum pressure ... through the slit channel' and 'for generating positive pressure ... through the slit channel' it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not

differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex Parte Masham*, 2 USPQ F.2d 1647 (1987).

As for **claim 4**, Spence discloses everything as above (see **claim 1**). In addition, he discloses the slit channel is optically transparent and has a clearance with a rectangular shape (col. 31, lines 30-40; Figs. 14a-14b demonstrate a rectangular detection region; Fig. 4b and Fig. 5 demonstrate rectangular segments).

As for **claim 5**, Spence discloses everything as above (see **claim 1**). In addition, he discloses the kit is made of a transparent material (col. 31, lines 30-40).

As for **claim 6**, Spence discloses everything as above (see **claim 1**). He does not explicitly state a heat control device; however, he suggests this by mentioning the dependence of diffusion on temperature (col. 26, lines 40-55). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to have a heat control device in order to keep temperature constant and therefore diffusion constant for proper cell sorting.

As for **claims 9 and 10**, Spence discloses everything as above (see **claim 1**). In addition, he discloses the image capturing unit is a CCD camera (Fig. 8: ccd camera) and the laser may be a laser diode (col. 4, lines 18-20).

10. **Claims 7-8** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Spence et al. (6,540,895)** in view of **Bessis et al. (3,955,890)**.

As for **claims 7-8**, Spence discloses everything as above (see **claim 1**). In addition, Spence discloses the image capturing unit, CCD camera, captures images, by projecting on the video screen (**claim 7**)(Fig. 8: ccd camera and video); and discloses capturing the images without projecting on the screen (**claim 8**)(Fig. 8: ccd camera receives images directly from

beamsplitter). As for diffracted images, Spence is silent. However, Bessis in a blood cell inspection system teaches that cells upon illumination of laser light produce diffracted images (col. 3, lines 50-55). Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made that diffracted images were captured for the blood was illuminated by a laser.

Allowable Subject Matter

11. **Claim 11** would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

As to **claim 11**, the prior art of record, taken alone or in combination, fails to disclose or render obvious in measurement unit the control unit calculates blood cell deformability and shearing force as a function of time according to pre-calculated data instead of applying instantly measured pressure data in combination with the rest of the limitations of **claim 11**.

Fax/Telephone Numbers

If the applicant wishes to send a fax dealing with either a proposed amendment or a discussion with a phone interview, then the fax should:

- 1) Contain either a statement "DRAFT" or "PROPOSED AMENDMENT" on the fax cover sheet; and
- 2) Should be unsigned by the attorney or agent.

This will ensure that it will not be entered into the case and will be forwarded to the examiner as quickly as possible.

Papers related to the application may be submitted to Group 2800 by Fax transmission. Papers should be faxed to Group 2800 via the PTO Fax machine located in Crystal Plaza 4. The form of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CP4 Fax Machine number is: (571) 273-8300

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gordon J. Stock whose telephone number is (571) 272-2431. The examiner can normally be reached on Monday-Friday, 8:00 a.m. - 6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gregory J. Toatley, Jr., can be reached at 571-272-2800 ext 77.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gs
October 29, 2007

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9/29/07